

EXHIBIT 18

Indianapolis, IN

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL) MDL No. 1456

INDUSTRY AVERAGE WHOLESALE) Master File No.

PRICE LITIGATION) 01-CV-12257-PBS

-----) Subcategory Case

THIS DOCUMENT RELATES TO:) No. 06-11337

United States of America ex)

rel. Ven-A-Care of the) Hon. Patti B. Saris

Florida Keys, Inc., et al.)

v. Dey, Inc., et al., Civil)

Action No. 05-11084-PBS, and) VIDEOTAPED DEPOSITION

United States of America ex) OF THE INDIANA FAMILY

rel. Ven-A-Care of the) AND SOCIAL SERVICES

Florida Keys, Inc., et al.) ADMINISTRATION by

v. Boehringer Ingelheim) CARL MARK

Corp., et al., Civil Action) SHIRLEY, R.Ph.

No. 07-10248-PBS) VOLUME I

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DECEMBER 2, 2008

INDIANAPOLIS, INDIANA

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EXHIBITS (CONTINUED)			Page 6	Page 8
NUMBER	DESCRIPTION	PAGE		
Exhibit Dey 509 - State Plan Amendment, IN-00000100 - 0120.....	246		1 defendants Dey, Inc., Dey L.P., Inc. and Dey, L.P.	
Exhibit Dey 510 - Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products, HHD022-0318 - 0333.....	302		3 MR. BIPPUS: And -- go ahead.	
Exhibit Dey 511 - Excessive Medicare Reimbursement for Ipratropium Bromide Report.....	339		4 MR. COOK: I'm Christopher Cook from Jones Day representing Abbott.	
			5 MR. BIPPUS: And Gary Bippus from the Office of the Indiana Attorney General.	
			6 MR. LINNEWEBER: Scott Linneweber, L-I-N-N-E-W-E-B, as in boy, E-R, Family and Social Service Administration.	
			7 MS. ST. PETER-GRIFFITH: Ann St. Peter- Griffith from the United States Attorney's Office, Southern District of Florida on behalf of the United States.	
			8 VIDEOGRAPHER: Will our court reporter please swear or affirm the witness.	
			9 CARL MARK SHIRLEY, R.Ph., having been first duly sworn to tell the truth, the whole truth, and nothing but the truth, relating to said matter, was examined and testified as follows:	
PROCEEDINGS			Page 7	Page 9
VIDEOGRAPHER: On the record at 9:07 a.m. on December 2nd, 2008. Here begins the videotaped deposition of Mark Shirley on behalf of the State of Indiana Family and Social Services Administration.			1 EXAMINATION	
This case regards the Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, in the United States District Court, District of Massachusetts.			2 BY MR. DOUGLAS JULIE:	
This deposition is taking place at the Hilton Hotel, 8181 N. Shadeland Avenue, Indianapolis, Indiana.			3 Q. Good morning, Mr. Shirley. Thank you for making yourself available today. Can I ask you to please state and spell your name for the record.	
My name is James David, Certified Legal Video Specialist. And our court reporter is Dana Miller. We're both working with Henderson Legal Services.			4 A. Yes. My name is Carl Mark Shirley, that's C-A-R-L M-A-R-K S-H-I-R-L-E-Y.	
Will our counsel please state your appearance for the record.			5 Q. Thank you. And are you here today to - are you here today on behalf of the Indiana Family and Social Services Administration?	
MR. JULIE: My name is Douglas Julie from Kelley, Drye & Warren. And I'm counsel for			6 A. Yes.	
			7 Q. You're their corporate designee?	
			8 A. Yes.	
			9 Q. Thank you. As I stated before, my name is Douglas Julie. I'm counsel for Dey, Inc., Dey, L.P., Inc. and Dey, L.P. I'll refer to those three collectively today as Dey.	
			10 Are you currently on any medications which might affect your memory?	
			11 A. No.	

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<p style="text-align: right;">Page 30</p> <p>1 MR. JULIE: Yes. 2 MR. BIPPUS: All right. 3 BY MR. JULIE: 4 Q. Are you, Mr. Shirley, are you prepared 5 to testify to all of the topics contained in 6 Exhibit 1 of this subpoena? 7 A. Yeah. 8 MS. ST. PETER-GRIFFITH: Object to the 9 form. Go ahead. 10 A. Again, to the extent I have knowledge. 11 Q. And I guess going back to what Gary 12 said, have you seen that the State of Indiana has 13 designated portions of Mr. Sharp's testimony as 14 responsive to the -- from his prior deposition as 15 responsive to the subpoena? 16 A. I do not understand your question. 17 Q. I received a document this weekend from 18 Mr. Bippus stating that the State of Indiana was 19 designating portions of Mr. Sharp's testimony as 20 responsive to this deposition (sic) in addition 21 to your testimony here today being responsive to 22 this subpoena.</p>	<p style="text-align: right;">Page 32</p> <p>1 it chief pharmacist. 2 Q. And what does your job entail? 3 A. As the title implies, it's operations 4 management. And myself with other staff have 5 oversight of contractors. 6 We have contractors that perform a 7 variety of services. In fact, the Indiana 8 Medicaid pharmacy benefit is heavily contracted 9 out. So a lot of it has to do with oversight and 10 management of contractors, making sure that we 11 get deliverables on time, monitoring for quality. 12 My position also calls for oversight of 13 the state's drug utilization review board and 14 therapeutics committee meetings. And those are 15 meetings of advisory bodies to the office. 16 There's also a quality advisory 17 committee which has to do with policy pertaining 18 to mental-health drugs. I have an assisting role 19 in that. 20 I'm over the oversight of the federal 21 and state supplemental rebate programs. And that 22 is, once again, back to the contractor oversight</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Okay. 2 Q. Do you understand that? 3 A. Now that you've told me. 4 Q. Okay. Well, having not -- had you not 5 heard that before? 6 A. No, I was not aware of that. 7 Q. Okay. So do you -- you have not been 8 told that your designation as Indiana Medicaid's 9 witness is limited by -- in any way by the 10 designation of Mr. Sharp's testimony? 11 A. Again, I'll ask you to restate that 12 question. 13 Q. Sure. You have not been instructed by 14 counsel that your designation as the witness for 15 Indiana Medicaid here is in any way limited by 16 Indiana's decision to designate Mr. Sharp's 17 testimony? 18 A. That was not communicated to me. 19 Q. Thank you. What is your position with 20 Indiana Medicaid? 21 A. It's Pharmacy Operations Manager, is 22 the title. I believe the job description calls</p>	<p style="text-align: right;">Page 33</p> <p>1 function. That is handled on a day-to-day basis 2 by our contractor, ACS. 3 Q. I'm sorry, is ACS an acronym or is -- 4 A. Stands for Affiliated Computer Systems. 5 Q. Thank you. And what does ACS do for 6 the state? 7 A. ACS is our designated PBM services 8 vendor. And in that capacity, they provide for 9 prior authorization services, preferred drug 10 lists support, related report development, and 11 the federal and state supplemental rebate 12 programs administration. 13 Q. Has ACS served in that role for the 14 last 20 years for Indiana? 15 A. No. I believe since 2003, if memory 16 serves me correctly. 17 Q. Was there another company that served 18 in that role prior to 2003? 19 A. EDS had been our claims processor, some 20 people refer to it as PBM function, I don't 21 believe it was necessarily a PBM function in the 22 conventional sense, but they did handle our</p>

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1 claims processing for us and fiscal agent
 2 contractor responsibilities.

3 Q. Thank you. Does Indiana Medicaid still
 4 contract with EDS for any functions?

5 A. Yes, yes.

6 Q. What does Indiana Medicaid contract
 7 with EDS for currently?

8 A. In the sense of pharmacy, it's claims
 9 processing and provider relations support. They
 10 handle provider enrollment functions. And it's
 11 basically a claims-functioning process.

12 Q. And for how long has EDS, generally has
 13 EDS provided claims-processing services to
 14 Indiana?

15 A. I can't tell you any specific number of
 16 years. EDS has been a claims processor for
 17 Indiana Medicaid for some time.

18 There was a period of time during which
 19 ACS at the beginning of their contract as PBM
 20 services vendor did provide claims support, and
 21 that was subsequently then returned backed back
 22 to EDS.

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1 So EDS has processed and adjudicated
 2 claims for some time with the interruption during
 3 which -- or the period of time during which ACS
 4 handled the claims processing.

5 Q. Thank you. How long have you been in
 6 your current position at Indiana Medicaid?

7 A. Since November of 1981.

8 Q. Prior to November 1981, did you have a
 9 different position at Indiana Medicaid?

10 A. Yeah, I should probably clarify that.
 11 Since November of '81, I've been an employee of
 12 the State. Had always been with the pharmacy
 13 benefit under the state Medicaid program.

14 Q. So have you had different titles since
 15 -- during that time?

16 A. Initially the title I came on as,
 17 quote/unquote, chief pharmacist. And I think
 18 that was primarily due to a position, just fill-
 19 in-the-block-type thing.

20 I don't think the state had ever had a
 21 pharmacist with the state Medicaid pharmacy
 22 benefit. I think the personnel situation called

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1 for pharmacists' positions primarily at state-
 2 operated facilities. And in those facilities,
 3 they would have had pharmacists and chief
 4 pharmacists. And in order to accommodate my
 5 salary needs at the time, they were able to get
 6 me in the position of chief pharmacist.

7 So while chief pharmacist was the block
 8 at the personnel level, I had been referred to as
 9 the pharmacist, the pharmacy consultant, and
 10 pharmacy director.

11 Q. Okay. And in that role as chief
 12 pharmacist, what were your responsibilities?

13 A. From the beginning, basically to handle
 14 anything regarding pharmacy. And that was at the
 15 outset retail pharmacy relations with retail
 16 pharmacies as providers. The state had just
 17 started a prior authorization program in 1981. I
 18 came on at the advent of that. I think that was
 19 one of the reasons for the creation of the
 20 position, was that they had prior authorization
 21 for certain services rendered by pharmacies.

22 So they needed a pharmacist to oversee

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1 and manage that. And anything having to do with
 2 pharmacy, per se, was in my scope of
 3 responsibilities.

4 Q. Okay. And did your -- has your title
 5 changed at any point?

6 A. Other than what I mentioned, no, it's
 7 been substantially the same.

8 Q. Thank you. Have you been employed
 9 continuously by Indiana Medicaid --

10 A. Yes.

11 Q. -- since 1981? Do you understand the
 12 time period that you're designated to testify to
 13 here today?

14 A. December '91 to present.

15 Q. Are you available to testify regarding
 16 facts that might have occurred in the 1980s?

17 MS. ST. PETER-GRIFFITH: I'm going to
 18 object to the form.

19 Q. You can still answer.

20 A. My answer to that would be no. I would
 21 not want to testify to something that would go
 22 that far back.

10 (Pages 34 to 37)

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<p style="text-align: center;">Page 142</p> <p>1 reimbursement amounts into ingredient portion and 2 a dispensing-fee portion?</p> <p>3 A. The reimbursement for pharmacy 4 reimbursement is comprised of estimated 5 acquisition cost plus dispensing fee, if 6 applicable, MAC plus dispensing fee, if 7 applicable, and usual and customary charge.</p> <p>8 So you had said aside from the state 9 MAC -- or excuse me, the usual and customary 10 piece, set that aside, then your two remaining 11 possible pieces of the algorithm would be EAC and 12 state MAC.</p> <p>13 Q. Okay. And on usual and customary-based 14 reimbursement, there is no dispensing fee paid to 15 providers?</p> <p>16 A. It's very important to understand that 17 the providers submit a charge, which is his usual 18 and customary charge, may or may not at that 19 provider's discretion include a dispensing fee. 20 That's totally up to the provider.</p> <p>21 Q. And if a provider submitted a claim 22 that contains a usual and customary charge, that</p>	<p style="text-align: center;">Page 144</p> <p>1 submit. We do not tell them bill us only for 2 some amount having to do with the drug and we, 3 Medicaid, will put a dispensing fee on top of 4 that. We never do that.</p> <p>5 Q. Okay. So -- all right, now I believe I 6 understand. So you're saying that when a 7 provider -- you know, I think you've said it. 8 There's no reason to summarize.</p> <p>9 A. It's complicated.</p> <p>10 Q. You stated that one of the ways that 11 Indiana reimburses for pharmaceuticals, Indiana 12 Medicaid reimburses for pharmaceuticals, is that 13 there is reimbursement for EAC --</p> <p>14 A. Yes.</p> <p>15 Q. -- and a dispensing fee. Is EAC 16 estimated acquisition cost?</p> <p>17 A. That's correct.</p> <p>18 Q. When considering the adequacy of reim - 19 - pardon me, strike that.</p> <p>20 When considering whether the state is 21 providing adequate reimbursement for a covered 22 product, does the state consider both the</p>
<p style="text-align: center;">Page 143</p> <p>1 -- I'm sorry. A provider can submit a claim that 2 expresses its usual and customary charge in two 3 parts, a part with a dispensing fee and another 4 part?</p> <p>5 A. No, we do not allow for that. The only 6 thing the program accepts and has instructed 7 providers is to submit their usual and customary 8 charge, which if the provider has a dispensing 9 fee of their own, that is part of their usual and 10 customary charge.</p> <p>11 Q. I'm not sure I understand what you mean 12 by dispensing fee with respect to usual and 13 customary charge.</p> <p>14 A. If a provider has a charge to you as a 15 customer, they're going to typically make that 16 charge up out of what they pay for the drug in 17 some fashion somehow, and something that they use 18 to cover their overhead and everything else 19 associated with the running of the pharmacy. 20 They blend that all together, and that becomes 21 their usual and customary charge.</p> <p>22 That's what we have told them to</p>	<p style="text-align: center;">Page 145</p> <p>1 ingredient portion and the dispensing-fee portion 2 as needing to be adequate?</p> <p>3 MS. ST. PETER-GRIFFITH: Object to the 4 form.</p> <p>5 Q. Do you think of those issues together 6 as providing that total reimbursement must be 7 adequate, or does reimbursement for each 8 individual component need to be adequate?</p> <p>9 MS. ST. PETER-GRIFFITH: Object to the 10 form.</p> <p>11 A. Once again, my sense on this is that 12 ultimately your reimbursement for the service 13 must be adequate to ensure participation by 14 providers. And my sense is that providers 15 probably don't much care one way or the other 16 which side of the equation is which, as long as 17 what they get from Medicaid is sufficient for 18 them to render service.</p> <p>19 So I think, you know, we act 20 administratively in light of that. It makes 21 sense to have a total reimbursement that is 22 sufficient to maintain provider participation.</p>

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<p style="text-align: right;">Page 234</p> <p>1 A. Yes.</p> <p>2 Q. Can you very briefly, because I may get 3 to this later, can you tell me your understanding 4 of the difference between brand and generic 5 drugs?</p> <p>6 What was Indiana's understanding of the 7 difference between brand drugs and generic drugs?</p> <p>8 A. Difficult to answer that question. The 9 difference between brand and generic drugs, 10 according to the FDA, is there is no difference.</p> <p>11 Generic drugs that are therapeutically 12 substitutable for brand-name drugs are the same. 13 But if you're talking about reimbursement, that's 14 a different issue. So I'm trying --</p> <p>15 Q. I am talking about reimbursement, sir.</p> <p>16 A. -- to find where you're going.</p> <p>17 Q. Thank you.</p> <p>18 A. So would you clarify the question.</p> <p>19 Q. Sure. This document, we've said, 20 distinguishes between brand-name drugs and 21 generic drugs for purposes of reimbursement; 22 that's correct?</p>	<p style="text-align: right;">Page 236</p> <p>1 look at this, this and this equals generic, if 2 you look at this, it's brand name.</p> <p>3 Q. Thank you. On this document it also 4 appears that the state has instituted for the 5 first time a state Maximum Allowable Cost 6 program?</p> <p>7 A. Yes.</p> <p>8 Q. Is that -- is this your recollection as 9 to chronologically the origin of the state MAC 10 program?</p> <p>11 A. Yes.</p> <p>12 Q. And charges for federal upper limit and 13 usual and customary-based reimbursement have been 14 retained --</p> <p>15 A. Right.</p> <p>16 Q. -- in this plan?</p> <p>17 A. Yes.</p> <p>18 Q. Thank you. I'm going to ask you about 19 the state MAC program a little later, but can I 20 ask you now, why did Indiana switch from an AWP 21 minus 10 EAC for all legend drugs to a bifurcated 22 AWP minus 13 for brand-name drugs and AWP minus</p>
<p style="text-align: right;">Page 235</p> <p>1 A. Yes.</p> <p>2 Q. By generic drugs, does the plan mean to 3 reimburse at a separate rate for innovator drugs 4 and non-innovator drugs?</p> <p>5 A. In looking at this document, the only 6 thing I can say is that there is clearly a 7 difference in policy as to how the state is going 8 to reimburse for brand-name drugs and for generic 9 drugs.</p> <p>10 Q. Okay. If I was a provider or I worked 11 for EDS and I wanted to know which drug fit the 12 brand-name formula and which drug fit in for the 13 generic formula, how would I go about determining 14 that?</p> <p>15 A. I believe that would come from the 16 First DataBank file that they use in claims 17 processing.</p> <p>18 Q. So the distinction here is a 19 distinction drawn on -- from First DataBank?</p> <p>20 A. First DataBank and if there is any 21 algorithm that would be developed to pay elements 22 from the First DataBank file that says if you</p>	<p style="text-align: right;">Page 237</p> <p>1 20 for generic drugs?</p> <p>2 A. I believe at the time the perception 3 was that generic drugs, AWP information was not 4 as accurate for generic drugs as it was for 5 brand-name drugs, that is there was a greater 6 spread on generic drugs.</p> <p>7 And if I also remember, it seems like 8 there was some input from other states that using 9 AWPs on generic drugs, you should have a higher 10 percentage off of your AWP for your EAC.</p> <p>11 Q. When you say generic drug -- I'm sorry, 12 strike that.</p> <p>13 You had stated that AWP information was 14 not as accurate, though you didn't specify by 15 what reference you were measuring its accuracy. 16 Can you just tell me a little bit about what you 17 were --</p> <p>18 A. I think there was a general perception 19 that the AWPs for generic drugs were inflated. 20 Seems like there was also some information from 21 OIG or GAO or both or CMS or all three that 22 questioned the use of AWPs on generics. And,</p>

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<p style="text-align: right;">Page 238</p> <p>1 again, I'm going strictly by memory on this. 2 It seems like that was part of the 3 thrust behind the bifurcation of the 4 reimbursement methodology for the two different 5 types of legend drugs.</p> <p>6 Q. But you had specifically used the word 7 that it was not as accurate. And it may very 8 well be that you did not mean to use the word. 9 But I'm just wondering whether when you said 10 accurate, if you were considering whether AWP -- 11 when you think about AWP accuracy, with what are 12 you referencing it as a guidepost? If something 13 is inaccurate, it must be --</p> <p>14 A. I think it all has to do with this 15 issue that people have called the spread, the 16 relationship between the published AWP of a drug 17 and an amount that a provider actually ends up 18 paying for the drug.</p> <p>19 And it seemed like for generics, it was 20 the case that there was this greater spread 21 between the AWP and the actual acquisition cost. 22 And I think that was probably what was behind the</p>	<p style="text-align: right;">Page 240</p> <p>1 which would have been 2002, and again I'm 2 thinking of Myers & Stauffer's role, they 3 typically provided analytic support to the office 4 on cost-containment initiatives. And this was 5 probably driven partially at least by some type 6 of cost-containment initiative. There may have 7 been information provided by Myers & Stauffer one 8 way or the other about, you know, this is where 9 the other states are on generics, and this is 10 what the market looks like, and this is what this 11 study shows. I don't know that for a fact one 12 way or the other.</p> <p>13 It could be, possibly not, but that's 14 one possible source of additional information, 15 would have been input from Myers & Stauffer.</p> <p>16 Q. Can you think of any other 17 considerations that Indiana made at the time?</p> <p>18 A. Well, obviously, going through the 19 rule-promulgation process, we would have 20 considered all public comments.</p> <p>21 And not knowing right here what the 22 public comments were that were made during the</p>
<p style="text-align: right;">Page 239</p> <p>1 taking generics to go to a minus 20 percent as 2 opposed to say the minus 13 1/2.</p> <p>3 Q. Because Indiana wanted to get closer to 4 -- get AWP-based reimbursement closer to the 5 spread -- I'm sorry, strike that.</p> <p>6 Did you understand -- I'm sorry, did 7 Indiana Medicaid understand at the time that it 8 moved in 2002 from AWP to minus 10 to AWP minus 9 20 for generics, did Indiana understand that it 10 was not necessarily capturing all of the spread 11 between average wholesale price and average 12 acquisition costs in discounting average 13 wholesale price?</p> <p>14 A. Repeat that question.</p> <p>15 Q. Did Indiana understand that when it 16 moved in -- I'm sorry, strike that.</p> <p>17 Can you think of any other 18 considerations that Indiana made other than 19 information disclosed from CMS that caused it to 20 make this switch to -- both to bifurcate brand 21 and generic and to switch to generic minus 20?</p> <p>22 A. Looking at the time frame of this,</p>	<p style="text-align: right;">Page 241</p> <p>1 public hearing for the initiative, it's possible 2 that there would have been other comments from 3 the public. And the record of the public 4 hearing, I'm sure, would show that.</p> <p>5 Q. What role did Indiana's understanding 6 of the prices at which pharmacies could obtain 7 pharmaceutical products play into the decision to 8 reduce the reimbursement for generic drugs to 9 minus 20 percent?</p> <p>10 A. State that again, please.</p> <p>11 MR. JULIE: Can you re-read that. 12 (The requested material was read 13 back by the reporter.)</p> <p>14 A. I quite sincerely do not understand the 15 question.</p> <p>16 Q. Okay. Then I'll reask it a different 17 way. When Indiana decided to reimburse for 18 generic drugs at AWP minus 20 percent, did it 19 consider in that decision-making process its 20 knowledge of pharmaceutical prices available to 21 provider pharmacies?</p> <p>22 A. I'm not certain of the analytic</p>